ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Outside Booklet Label (tear open label)
250 ml, 1L and 3 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluboral 200 mg/ml, suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Flubendazole 200.0 mg

3. PACKAGE SIZE

250 ml, 1L and 3 L

4. TARGET SPECIES

Pigs and chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Pigs:
Meat and offal: 1 mg/kg for 5 days: 4 days
2.5 mg/kg for 2 days: 5 days
Chickens:
Meat and offal: 2 days
Eggs: zero days

8. EXPIRY DATE

EXP {month/year}

Shelf life after first opening: 6 months.

Once opened use by __/__
Once diluted use within 24 hours.

9. SPECIAL STORAGE CONDITIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/3000

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

Inside Booklet Label (tear open label)
250 ml, 1L and 3 L

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Fluboral 200 mg/ml, suspension for use in drinking water for pigs and chickens

2. Composition

Each ml contains:

Active substance:
Flubendazole 200.0 mg

Excipients:
Methyl parahydroxybenzoate (E218) 2.7 mg
Propyl parahydroxybenzoate 0.75 mg

White to off-white suspension

3. Target species

Pigs and chickens.

4. Indications for use

Chickens:
Treatment of helminthiasis caused by:
- *Ascaridia galli* (adult stages)
- *Heterakis gallinarum* (adult stages)
- *Capillaria* spp. (adult stages)

Pigs:
Treatment of helminthiasis caused by *Ascaris suum* (adult and L4 intestinal stages)

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Optimal results can only be achieved if strict rules of hygiene are applied.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product can cause skin and eye irritation, and hypersensitivity reactions.
Direct contact with the product should be avoided. People with known hypersensitivity to flubendazole should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.
In the event of eye contact, rinse thoroughly with water and if conjunctival redness persists, seek medical advice.

Special precautions for the protection of the environment:
Due to concerns for the environment when the product is used in free range poultry or pigs, animals must be kept indoors during the treatment period and for 1 day after last treatment.

Pregnancy and lactation:
Laboratory studies in rabbits and rats have not produced any evidence of embryotoxicity, teratogenicity at therapeutic doses. High dosages gave equivocal results. In laboratory studies in rats, there were no effects on pups during lactation.
The safety of the veterinary medicinal product has been established during pregnancy, lactation and lay. Can be used during pregnancy and lactation.

Laying birds:
Can be used during lay.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
In chickens, no undesirable effects have been observed after administration of up to 4 times the recommended dose for 14 days. Even at doses 4 times the recommended dose, egg quality is not altered. Only a reduction in egg weight and a slight decrease in egg production can be observed with doses of twice the recommended dose and over. Egg weight returns to normal when treatment is discontinued.

In pigs, no undesirable effects have been observed at five times the highest dose administered for three times the intended duration (12.5 mg/kg administered for 6 consecutive days).
In the event of a massive overdose, mild transient diarrhoea can occur by the 2nd day of treatment, possibly lasting for 7 to 12 days without affecting the behaviour or performance of the animals.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Chickens:
Undetermined frequency (cannot be estimated from the available data): Development disorders of the feathers.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

In drinking water use.

Dosage:

Chickens:
1.43 mg flubendazole (= 0.00715 ml product or 0.00775 g product) per kg body weight daily for 7 consecutive days, administered orally in drinking water, i.e. 1 ml of the product per 140 kg body weight daily for 7 days.

Pigs:
a. Treatment of adult stages and L4 intestinal stages of *Ascaris suum*
1 mg flubendazole (= 0.005 ml product or 0.00542 g product) per kg body weight daily for 5 consecutive days, administered orally in drinking water, i.e. 1 ml of the product per 200 kg body weight daily for 5 days.

b. Treatment of adult stages of *Ascaris suum*
2.5 mg flubendazole (= 0.0125 ml product or 0.0136 g product) per kg body weight daily for 2 consecutive days, administered orally in drinking water, i.e. 2.5 ml of the product per 200 kg body weight daily for 2 days.

Based on the recommended dose and the number and weight of animals to be treated, the required daily volume of veterinary medicinal product should be calculated according to the following formula:

$$\text{ml of veterinary medicinal product required per day} = \frac{\text{Dose (mg/kg BW)} \times \text{Total BW (kg) of animals to be treated}}{\text{200 mg/ml (concentration of the veterinary medicinal product)}}$$

In case a weighing scale is used:
g of product required per day = ml of product required per day x 1.084

Method of administration:

Prior to and after the period of treatment make sure the water distribution system is cleaned.
Each day a fresh suspension should be prepared.
The container should be shaken for 30 seconds before use.

1. Tanks:
   Add water to the daily required amount of product until the volume equals the quantity of water usually consumed by the animals in approximately 4 hours.
2. Dosing pumps:
   Prepare a stock suspension according to the flow rate of the pump. For example: at a 1% flow rate add water to the daily required amount of product until the volume equals 1% of the quantity of water usually consumed by the animals in approximately 4 hours. The maximal concentration of the product in the drinking water should be 150 ml/L.

9. Advice on correct administration

Stir with a manual mixer (whisk) for about 5 seconds to obtain a white milky homogenous mixture.

In order to ensure administration of the correct dose, a substantial water flow must be present in the drinking water system:
-administer the product when the water consumption of the animals is highest
-if needed withhold drinking water for 2 hours before treatment to stimulate water intake

Make sure the medicated water is fully consumed to avoid underdosing. The exact time period over which the product is administered each day is not critical but all animals should have sufficient time to drink.
Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked. The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Pigs:
Meat and offal: 1mg/kg for 5 days: 4 days
2.5mg/kg for 2 days: 5 days
Chickens:
Meat and offal: 2 days
Eggs: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
The veterinary medicinal product should not enter water courses as flubendazole may be dangerous for fish and other aquatic organisms.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems.
These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

250 ml, 1L and 3L
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

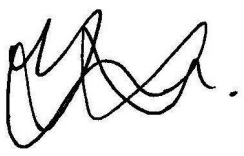
Marketing authorisation holder and contact details to report suspected adverse reactions:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
+44 (0) 1939 211200

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information



Approved 04 May 2023